

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Heinrich Kladders, et al.

Group Art Unit: 3771

Application No.: 10/757,346

Examiner: MATTER, Kristen

Filed: January 14, 2004

Confirmation No.: 3492

For: POWDER INHALER

Atty. Docket No.: 1/1447

DECLARATION OF HEINRICH KLADDERS

I, Heinrich Kladders, declare that:

1. I am a co-inventor of the invention disclosed and claimed in U.S. Patent Application No. 10/757,346.

2. I have been a chemical engineer for over 30 years, and I have been designing medicament distribution devices, including powder inhaler devices, aerosol devices; related devices, methods and tooling for over 25 years. I have been associated with one of the major international pharmaceutical companies, Boehringer Ingelheim International GmbH of Ingelheim, Germany, for more than 30 years.

3. I am a named inventor in about 20 published patent applications in the U.S. – not including foreign patents/applications – involving powder inhaler devices, aerosol devices; related devices, methods and tooling. I have reviewed and have been involved in reviewing and evaluating numerous U.S. patents and pending U.S. patent applications in connection with patentability.

4. I received a degree in chemical engineering from the “Technikerfachschule Duisburg” located in Duisburg, Germany in 1968.

5. Due to my years of experience in design and product development, my involvement in patent issues, and my education, I have developed significant skill in the technologies related to powder inhaler devices, aerosol devices; related devices, methods and tooling. I am well versed in what skilled artisans know as a matter of common knowledge and what they would understand from the teachings of a publication, such as a U.S. patent/application.

6. I have reviewed the following U.S. Patents and Published Patent Applications cited against U.S. Patent Application No. 10/757,346:

U.S. 5,947,118 to Hochrainer ("the '118 patent");

U.S. 5,871,010 to Datta et al. ("the '010 patent");

U.S. 5,472,143 to Bartels et al. ("the '143 patent"); and

U.S. 4,889,114 to Kladders ("the '114 patent").

7. I have reviewed the '118, '010, '143, and '114 patents and conclude that the teachings of the subject patents, alone or in combination, do not disclose or suggest sloped and/or tapered parabolic-shaped elevations and/or depressions in a repeating pattern of an egg-carton arrangement. The raised areas and indentations of the '010 patent have valley walls that are perpendicular to the plane of the surface (*e.g.*, surface of the substrate 86) of the device (see col. 5, lines 21-26; col. 8, lines 22-34; and FIGS. 3A-8B), and are not sloped and/or tapered. The '118, '143, and '114 patents lack sloped and/or tapered elevations and/or depressions as claimed. As such, the structures of the subject patents, alone or in combination, are different from the structure as recited in independent claim 1 of U.S. Patent Application 10/757,346.

8. The aforementioned structural differences between the device of the '010 patent and the present invention as recited in independent claim 1 of the instant application are critical because the structure of the surface walls affects the amount of interaction between the particles and the inhaler surface. The specification of the instant application as originally filed clearly establishes the criticality of the structure of claim 1 and the associated surprising and unexpected results. In particular, the specification of the instant application states:

[s]urprisingly, it has now been found that powder inhalers in which at least part of the inner surfaces which may come into contact with the powder aerosol are provided with a micro- or nano-structured surface, do not have worse delivery characteristics than powder inhalers with a smooth inner surface in these areas. (Page 5, lines 25-30, emphasis added.)

Moreover, the specification of the instant application states that “[t]he properties of the surfaces thus obtained are optimum when the elevations have rounded tips.” (Page 22, lines 1-5.) Indeed, rounded tips have a sloped/tapered parabolic shape.

9. One skilled in the art would not be motivated to modify the raised areas and indentations of the ‘010 patent to be sloped and/or tapered. Changing the shape of the indentations of the device of the ‘010 patent from valley walls that are perpendicular to the plane of the surface (*e.g.*, surface of the substrate 86) to walls that are sloped and/or tapered is not an obvious design consideration. Sloped and/or tapered grooves are not well known and are not commonly used with microtechnology fabrication.

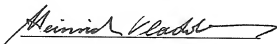
10. The ‘010 patent teaches away from modifying the raised areas and indentations of the ‘010 patent to be sloped and/or tapered because the ‘010 patent teaches minimization of contact between particles and the surface (*e.g.*, surface of the substrate 86) of the device of the ‘010 patent. A change in the shape of the raised areas and indentations of the device of the ‘010 patent to be sloped and/or tapered would change the function of the raised areas and indentations because sloped and/or tapered raised areas and indentations would not minimize the contact between the particles and a surface. The ‘010 patent teaches decreasing the contact area such that the contact is minimized so particles are more likely to be released from the surface of the substrate (*e.g.*, substrate 86) of the ‘010 patent device (see col. 5, line 10 through col. 6, line 25; col. 8, lines 22-34; and FIGS. 8A-8B). One skilled in the art reviewing the ‘010 patent would understand that the “decrease” teaching is intertwined with, and inseparable from, the teachings of minimization. After all, decreasing contact between the particles and the surface of the device of the ‘010 patent is a necessary step of the minimization process (*i.e.*, to minimize, a decrease must occur).

DECLARATION OF HEINRICH KLADDERS

Page 4

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: August 25, 2009

A handwritten signature in black ink, appearing to read "Heinrich Kladders", written over a horizontal line.

By: Heinrich Kladders

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